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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/890,097 | 10/29/2001 | Hiroyuki Tokunaga | 0020-4885P | 5983 |

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1753

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,097

Applicant(s)

TOKUNAGA ET AL.

Examiner

ALEX NOGUEROLA

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1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Claim Rejections - 35 USC § 112

1. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

- a) Claim 1, line 9: what are “objective samples”?
- b) Claim 1, line 15: -- of the objective samples -- should replace “sample”;
- c) Claim 6, lines 1-2: what does it mean for a sensor system to be judged “right”?
- d) Claim 6: how is the “quantitated value of the concentration of the target substance contained in the control fluid” related to the discrimination function? Is this a separate calculation? As it currently reads, the judging of Claim 6 does not appear to be related to the discrimination function of the method of claim 1;
- e) Claim 6 recites the limitation " the target substance contained in the control fluid " in lines 3-4. There is insufficient antecedent basis for this limitation in the claim.
- f) the judging step should be in the active voice (-- judging whether --);
- g) Claim 7, line 3: -- such -- should be inserted before “the”;
- h) Claim 7, line 3 and Claim 1, line 3: should -- objective -- be before “sample”? and
- i) Claim 7, line 5: “purport” means intention or purpose. The purport of “purport” in this claim is not clear?

2. Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 5, 6, and 7 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by the JPO machine translation of Yuichiro et al. (JP 11-230934), hereafter “the Yuichiro et al. reference.” Note that although Inoue Yoichi is listed as a co-inventor in the declaration of the instant application and on the first page of the Yuichiro et al. reference, Noda Yuichiro is not listed as a co-inventor in the declaration of the instant application, but is listed as a co-inventor on the first page of the Yuichiro et al. reference. Thus, the Yuichiro et al. reference is by another (MPEP 715.01(a)).

Addressing claim 1, The Yuichiro et al. reference teaches a method of discriminating a sample for a sensor system which quantitates the concentration of a target substance contained in the sample by measuring electric current (abstract), the method comprising

using a ratio of a measured current value to a time-differential value of the current value as a discriminating parameter (paragraph [0013] of the *Detailed Description*);

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defining a discrimination function for discriminating kinds of a plurality of objective samples, the discrimination function using the discriminating parameter as an independent variable (paragraph [0013] of the *Detailed Description*);

using a numeric value obtained by substituting the value of the discriminating parameter into the discrimination function, as a discriminating index (paragraphs [0013]-[0016] of the *Detailed Description*); and

discriminating the kind of any sample base on the discriminating index (paragraphs [0013]-[0016] of the *Detailed Description*).

Addressing claim 2, using a plurality of discriminating parameters in the discrimination function is taught in (paragraph [0014] of the *Detailed Description*).

Addressing claim 3, using a linear expression to define the discrimination function is taught in (paragraph [0014] of the *Detailed Description* and paragraph [0020] of *Embodiments of the Invention*).

Addressing claim 5, discriminating blood from as control sample is taught in paragraphs [0017] to paragraphs [0022] of *Embodiments of the Invention*.

Addressing claim 6, judging the sensor system as claimed is taught in paragraphs [0019] to paragraphs [0022] of *Embodiments of the Invention*.

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Addressing claim 7, alternative outputs are taught in paragraph [0016] of the Detailed Description.

Allowable Subject Matter

5. Claim 4 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 4 requires that the discrimination function be defined by means of an expression of high degree for the discriminating parameter. The Yuichiro et al. reference only discloses linear expressions for the discrimination function, that is, expressions of only the first degree.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguera

Alex Noguera

9/11/2003

Primary Examiner

TC1700